

Remarks

Reconsideration of this Application is respectfully requested.

Claims 1-17 are pending in the application, with claim 1 being the independent claim. The Examiner withdrew claims 6, 7 and 10-13 from consideration.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-5, 8, 9 and 14-17 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. (*See* Office Action, p. 2.). The Examiner's *entire* argument in support of the rejection is as follows:

The claims(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification fails to provide an adequate disclosure for the "phenyl pyrazoline derivatives". The only compound listed in the specification is BW 755c.

(Office Action, p. 2.). Applicants respectfully disagree with the rejection and traverse.

In an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability. This burden is *only* discharged if the Examiner can present evidence or reasons why one skilled in the art would *not* reasonably conclude that Applicants possessed the subject matter as of the priority date of the present application. *In re Wertheim*, 541 F.2d 257,

262, 191 U.S.P.Q.2d 90, 96 (C.C.P.A. 1976); M.P.E.P. § 2163.04. The Applicants submit that the Examiner has merely presented a conclusory argument that is unsupported by the evidence of record and fails to take into account the current state of the law regarding written description or the level of skill in the art. Thus, the Examiner's burden clearly has not been met.

To satisfy the written description requirement, the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-1564 (Fed. Cir. 1991). A specification need not disclose what is well known to those skilled in the art and preferably omits that which is well known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986). In addition, when generic elements of a claim are so well known and thoroughly characterized in the art that their recitation alone is sufficient to convey distinguishing information regarding their identity, the written description requirement for those elements is fully satisfied. *See Amgen Inc. v. Hoechst Marion Roussel Inc.*, 65 U.S.P.Q.2d 1385, 1398 (Fed. Cir. 2003). Further, the written description requirement must be viewed in light of the state of the art at the time of filing. *Capon v. Eshhar*, 418 F.3d 1349, 1357-1358 (Fed. Cir. 2005) ("[t]he descriptive text needed to meet [the written description requirement] varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.").

The Federal Circuit, in *Capon*, made clear that there is no requirement to re-describe what is already known in the field. 418 F.3d at 1357-1358 ("None of the cases to which the Board attributes the requirement of total DNA re-analysis, *i.e.*, *Regents v. Lilly*, *Fiers v. Revel*, *Amgen [v. Chugai]*, or *Enzo Biochem*, require a re-description of what was already known."). In discussing the current state of the written description requirement under 35 U.S.C. §112, first paragraph, the Federal Circuit stated "[s]ince the law is applied to each invention *in view of the state of relevant knowledge*, its application will vary with differences in the state of knowledge in the field" *Capon*, 418 F.3d at 1357-1358 (emphasis added). In reviewing and overturning the Board's decision, the Federal Circuit held that "[t]he Board erred in refusing to consider the state of scientific knowledge" *Id.*

Furthermore, the Federal Circuit stated:

The "written description" requirement states that the patentee must describe the invention; it does not state that every invention must be described in the *same way*. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution. Both Eshhar and Capon explain that this invention does not concern the discovery of gene function or structure, as in *Lilly*. The chimeric genes here at issue are prepared from *known* DNA sequences of *known* function. The Board's requirement that these sequence must be analyzed and reported in the specification *does not add descriptive substance*.

Id. at 1358 (emphasis added). As such, written description does *not* require disclosure of a structure known in the field.

When viewed in light of the state of the art at the time of filing the present application, the ordinarily skilled artisan would readily recognize that the specification adequately supports the presently claimed invention. As an initial matter, Applicants note that only claims 5, 8 and 9 contain the term "phenyl pyrazoline derivatives." Claim 1, which is a generic linking claim, and claims 2-4 and 14-17, which depend either directly or indirectly from claim 1, do not contain the term. Applicants submit that the terms used in these claims have sufficient written description support in the specification. *See e.g.*, paragraphs [0032]-[0034], [0046] and [0051]-[0069], of the specification as filed. Generic linking claims must be examined with, and thus are considered part of, the invention elected. *See* M.P.E.P. § 809. Since the term "phenyl pyrazoline derivatives" is *not* used in claims 1-4 or 14-17, the written description rejection of these claims lacking the objectionable term is unsupported by *any* evidence.

Further, Applicants submit that the term "phenyl pyrazoline derivatives" would have been recognized by one of ordinary skill in the art as of the filing date of the pending application based on the well known use of such derivatives as inhibitors of the lipoxygenase pathway. For example, U.S. Patent No. 4,572,913 (**Exhibit A**) and U.S. Patent No. 4,465,685 (**Exhibit B**) disclose phenyl pyrazoline derivatives as inhibitors of the lipoxygenase pathway. As illustrative of the state of the art at or before the time of filing of the present application, Exhibits A and B disclose several examples of different phenyl pyrazoline derivatives inhibiting lipoxygenase in an enzyme assay. Likewise, these types of derivatives have been prepared by methods known in the art at least since 1954. *See J. Chem. Soc.* (1954), 408-415.

As in *Capon*, the presently claimed invention does *not* concern the discovery of a molecule's function or structure. The derivatives utilized in the claimed invention are a *known* class of molecules, with a *known* function (lipoxygenase inhibitors). Describing every phenyl pyrazoline derivative that could be used in the practice of the present invention would not add descriptive substance to the present application, and hence is not required under the analysis in *Capon*. Furthermore, the novel aspect of the invention is *not* the phenyl pyrazoline derivatives themselves; it is the *use* of these well known derivatives to treat elevated serum triglycerides or hypertension. Since the generic elements of the claims, reciting phenyl pyrazoline derivatives, are well known and characterized in the art, the written description requirement for that element of the claim is satisfied. *See Amgen Inc.*, 65 U.S.P.Q.2d at 1398 (holding that when generic elements of a claim are so well known and thoroughly characterized in the art that their recitation alone is sufficient to convey distinguishing information regarding their identity, the written description requirement for those elements is fully satisfied); *see also Capon*, 418 F.3d at 1358 (explaining when the art includes the relevant information, "precedent does not set a *per se* rule that the information must be determined afresh.").

The ordinarily skilled artisan would readily understand, based on the knowledge available in the art of the structure and uses of phenyl pyrazoline derivatives, that any phenyl pyrazoline derivative can be utilized in the practice of the presently claimed invention provided the derivative reduces elevated serum triglycerides or hypertension when given in an effective amount. Examples 1 and 2 in the present specification disclose the use of an exemplary phenyl pyrazoline derivative, BW 755c. This description of an exemplary representative species of a phenyl pyrazoline derivative

provides sufficient written description such that the skilled artisan would understand that the Applicants, at the time the application was filed, had full possession of the presently claimed invention. *See also, Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1073 (Fed. Cir. 2005) (holding that description of a single species is sufficient written description for claims directed to a modified polypeptide having DNA polymerase activity).

Applicants submit, therefore, that the state of the art as of the filing date of the present application was such that one of skill in the art would readily recognize that the inventors were in possession of the claimed phenyl pyrazoline derivatives. Accordingly, Applicants submit that the present specification adequately and sufficiently describes the presently claimed invention, and hence, fully meets the written description requirements of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all currently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

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